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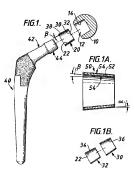
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(54) Dual composition coupler for modular medical implants.

(iii) The invention provides an interpositional coupler for inserting between modules of a modular medical implient, wherein successions are a fabricated of compositions having different electrochemical potentials, to reduce or prevent the flow of a galvanic current and thereby reducing or preventing this contribution to correction of the prosthesis. The coupler may be of an insulative type comprising a zizconium/zi-conium alloy core coated with blue-black visconium oxide or intride or any metal coated with amorphous diamond-tike carbon. Alternatively, the coupler may be of a dual composition they with each of the composition having essentially the same electrochemical potential as the module to which it couples.



This invention relates to modular medical implants and more specifically to multi-component prosthetic implants where interconnecting components are made of different metallic alloys and ceramics. More specifically, the invention provides a dual composition sleeve or interpositional device which, when interposed between components of a medical prosthesis, reduces or eliminates electrochemical activity and resultant galvanic corrosion that may occur between the two modular components in the body.

An increasing number of hip replacement prostheses are now based on modular designs. Typically, in such a design, the femoral head is a separate component that is press-fitted and locked onto the neck portion of the hip stem. The heads may be of inert alumina or zirconia ceramic but the most popular heads are those fabricated from a cobalt, stainless steel, or titanium alloy. Commonly, for non-cemented cases, the hip stem is made of the more flexible titanium alloys and the femoral head is made of a more abrasion resistant alloy such as a cobalt alloy. It is believed that this system gives the best long-term (non-cemented) performance. However, it has now been found that when such dissimilar alloys are used to form modules of the hip prosthesis then galvanic corrosion may contribute to dissolution of metal at the metal interface. The body fluids act as an electrolyte for the conduction of electrons and an associated low amperage current which results in electro-chemical corrosion of the alloys which may loosen the connection, and release metal ions into the body tissue.

In order to overcome this contribution of metal ions from galvanic corrosion in such modular press-fit connections, one might substitute a ceramic femoral head for the abrasion resistant cobalt alloy femoral heads. However, such a substitution, while solving the potential problem of galvanic corrosion, presents a potential new problem associated with relatively brittle ceramics: catastrophic failure of the ceramic head. For instance, US Patent No.4.921,500 points out that when ceramic materials are used in a femoral head component, they are more "frangible" than metals and it has been found that the standard taper connections, such as the Brown and Sharpe taper, establishes hoop stresses within the ceramic femoral head. When these hoop stresses exceed the strength of the ceramic material in tension, the solid ceramic femoral head may fail with catastrophic results. To overcome this stress problem, US Patent No.4,921,500 discloses as its invention an adaptor, fabricated of biocompatible alloy, such as titanium, having specified inner and outer taper for interposing between the borehole in the femoral head and the post on the neck of the femoral stem component. Such an adaptor is said to enable the securement of the ceramic femoral head to the post of conventional metallic femoral stems, providing a secure fit without the generation of excessive hoop stresses which could damage the ceramic femoral head.

The use of hard metallic femoral heads is however still preferred because of their resistance to damage caused by impact, greater ease of fabrication, and lower modulus of elasticity as compared to ceramics.

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British Patent No.GB2230192 shows a coupler for a prosthesis having a neck made of a first material and having a first taper, and a head made of a second material with a blind bore of a second taper. The coupler has an outer surface with a taper corresponding to the second taper for cooperating with the borehole and an inner surface with a taper corresponding to the first taper for cooperating with the neck. The outer surface texture of the coupler has a first degree of coarseness for tight coupling with the inner surface of the borehole in the femoral head component, Further, the inner surface of the coupler has a surface texture of a second degree of coarseness, different from the first degree of coarseness, for tight coupling with the outer surface of the neck of the femoral stem. In the preferred embodiment, the interpositional coupler is fabricated of a titanium alloy, Ti-6A1-4V. The patent does not anywhere address the problem of galvanic corrosion when two components of a prosthesis, each having a different metallic composition than the other, are joined together in the patient's body. Indeed, this problem, has only recently come to light.

It is now known that after 40 months of implantation galvanic assisted corrosion occurs in 100 percent of the cases where a cobalt alloy femoral head is coupled to a Ti- 6A1-4V hip stem. Although contribution from galvanic corrosion may be small for these metal combinations using proper design, it is yet desirable to reduce galvanic effects further. When the same material is used for both stem and head, no calvanic pitting corrosion is found. However, most surgeons prefer to use a harder, more abrasion resistant, metal alloy, such as the cobalt alloys, for the femoral head and a more ductile alloy. Ti-6A1-4V, for the hip stem.

What is yet needed is a method for the elimination of galvanic assisted corrosion that may occur in the body when a first component of a prosthesis having a first metal alloy composition is fixedly or removably attached to a second component of a prosthesis having a second, different metal alloy composition.

Whilst the discussion relates particularly to hip prosthesis it is clear to one skilled in the art that the problem of galvanic corrosion will arise at any prosthesis surface where different materials are utilised and an electrochemical reaction may therefore occur. Thus the present invention aims to overcome the problem of galvanic corrosion in hip prosthesis, knee prosthesis, bone fixation screws, etc.

The invention provides interpositional couplers for interposing between two modules of a modular medical implant prosthesis that have different electrochemical potentials thereby preventing or reducing

the flow of a galvanic current from one module to the other through the body fluid as an electrolyte and thereby eliminating or reducing galvanic assisted corrosion.

According to the invention we provide, a dual composition coupler for interposing between two components of a modular medical implant adapted for coupling with a first and a second component, comprising:

a first portion comprising a first metallic alloy that has an electrochemical potential substantially identical to that of the first component and

a second portion comprising a material different from the first metallic alloy which material prevents the build up of a galvanic charge between the first component and the second component.

According to the invention we further provide a dual composition coupler for interposing between two components of a modular medical implant comprising:

an outer first portion adapted for coupling with a first component, the outer portion comprising a first metallic alloy that has an electrochemical potential substantially identical to that of the first component against which the outer portion is designed to couple, and

an inner second portion comprising a second metallic alloy different from the first metallic alloy the second metallic alloy having substantially the same electrochemical potential as the second component against which the surface of the inner portion is designed to fit.

The coupler according to the invention may be a sleeve, e.g. a frusto conical sleeve. The sleeve may optionally be an individual dual composition member, or it may comprise a plurality of individual members which members may themselves be single or dual composition eg. comprising an inner and an outer sleeve. For example an inner frusto conical sleeve forms a snug fit inside an outer frusto conical sleeve forms a snug fit inside an outer frusto conical sleeve intis dual component sleeve being staped to fleet between the neck of a prosthetic hip joint stem and the bore hole in the femoral head. Alternatively, when the sleeve is for use in relation to, e.g. bone fixing screws, it may be a single or a dual component sleeve define a countersunk bore hole.

In one embodiment the invention provides a dual composition coupler or sleeve for interposing between the neck of a femoral stem component and the borehole of a metallic femoral head component to reduce or eliminate potential galvanic corrosion. The sleeve is fabricated of two metallic alloys. The first salloys is disposed on the outer surface while the same electroace alloy is the same as, or has the same electroace alloy is the same as, or has the same electroace alloy of the femoral beach component while the linner surface alloy is deficial to make the same electroace and potential as the alloy or has the same electroacemical potential as the alloy or has the same electroacemical potential as the alloy

that constitutes the femoral stem component. The dual composition coupler in effect comprises two metallic sleeves nested and bonded together coextensively so that no gap exists between their nesting surfaces for an electrolyte and no galvanic current passes between the two nested sleeves of the dual composition sleeve. Consequently, when the dual composition coupler is in place, galvanic assisted corrosion in the press-fit interface of either the dual composition coupler or the femoral head and femoral stem are eliminated.

To fabricate the dual composition coupler, a melallic bond may be accomplished by friction welding, high temperature diffusion bonding, brazing, or using other processes which will eliminate the possibility of a body fluid electrolyte interposing between the two surfaces of the nested sleeves thereby preventing a potential galvanic condition which leads to corrosion.

There is therefore provided a dual composition coupler for interposing between two components of a modular medical implant comortsino:

a) an outer sleeve portion having an outer surface adapted for coupling with a first component module, said outer surface comprising a first metallic alloy that has an electrochemical potential substantially identical to that of a first modular implant part against which the outer surface is designed to couple; and

b) an inner sleeve portion comprising a second metallic alloy different from the first alloy, the outer surface of said inner sleeve portion being coextensive with and nested tightly against the inner surface of the outer sleeve portion so that electrolyte solutions are precluded from entering between the inner and outer sleeve portion, the second alloy having substantially the same electrochemical potential as a second modular implant part against which the inner surface of the inner sleeve portion is designed to fit.

We further provide a coupler according to the invention which comprises an inner portion of a first metallic alloy which portion is coated on its component facing surfaces with a layer of material which prevents the build up of galvanic charge between the first component and the second component. Thus the coupler may comprise a first metallic alloy core an a surface coating or outer layer of a material which prevents the build up of galvanic charge. The outer layer may comprise a ceramic layer, eg. blue-black zirconium oxide, zirconium nitride or carbon.

According to the invention we also provide a dual composition coupler comprising an insulative sleeve for interposing between components of a modular medical implant, which sleeve comprises a zirconium or zirconium alloy metal substrate core and an in situ formed surface coating over said substrate core, said coating selected from the group of coatings consisting of blue-black zirconium oxide, zirconium nitride

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and carbon coatings, said sleeve being designed for interposing fit between two modules comprising materials of different electrochemical potential that the other such that, when said sleeve is interposed between the modules the sleeve insulates the two modules, from each other thereby substantially preventing calvaria cation.

In a second embodiment, an insulative coated sleeve is interposed between components of a modular prosthesis, trauma product, or other medical implant. This insulative sleeve or separator comprises a metal substrate with an outer surface comprising a ceramic that forms a barrier to electron exchange between two prosthesis modules. Thus, when the ceramic coated coupler fits over, for instance a screw, in a bone plate assembly, then it insulates the screw from the bone plate. These insulative couplers may be fabricated from any suitable metal for implants coated with a titanium nitride or other metal nitride or an amorphous diamond-like carbon coating. Alternatively, they may be fabricated from zirconium or its alloys coated with an in situ formed coating of blueblack zirconium oxide or zirconium nitride. The coating process is described in US Patent No.5,037, 048, hereby fully incorporated by reference. With regard to knee joints, a modular knee joint prosthesis is disclosed in US Patent No.4.950.298 to Gustilo et al., which is fully incorporated by reference. Further US Patent No.5,047,058, hereby fully incorporated by reference, shows inserts for the tibial component of a knee prosthesis. Neither of these patents describe a dual composition coupler designed to minimise or reduce galvanic corrosion effects.

According to the invention we also provide a ocupler as hereinbefore described having a surface and comprising a metal substrate from which the sleeve is fabricated and a coating over the surface of the sleeve, said coating selected from the group of coatings consisting of amorphous diamond-like carbon, metal nitrides and metal oxides.

In an alternative embodiment, a biocompatible metallic sleeve with an abrasion resistant inert, biocompatible, ceramic coating such as an oxide, nitride, or amorphous diamond-like carbon coating could also be used to electrically insulate the femoral stem from the head. Preferably, these nitride or oxide coatings are prepared in situ and have a thickness of not greater than about 5 microns. Such coatings are hard, tightly adherent to the underlying substrate and resistant to microfretting wear. Such ceramic coated sleeves are effective because, inter alia, the dense ceramic surface layer acts as an insulator between the underlying metal and metal modular part fitting against the inside and outside diameter of the sleeve, so that little or no electron exchange can take place. Thus, galvanic-related effects are eliminated.

Similar dual composition couplers could also be incorporated into other modular prostheses or trauma

products. For instance, these couplers could be used in the form of sleeves between bone plate holes and bone screw surfaces, or over postor extension pieces on modular hip and knee components or in the form of rectangular wedges of finish thickness between surfaces of modular components in contact with or in close proximity to other portions of such devices, such as knee joint modules. Also, couplers in the form of modular wedges may be used to alter the shape and fit of an implant. The same dual composition or insulator coupler concepts may also be applied to other non-orthopedic medical implants such as between metal components in cardiovescular, dental, or otology implants.

The drawings show certain specific embodiments of the invention but are not intended to be limiting of the invention. Further, the drawings are schematic and representational and are not to scale.

The invention provides an interposition coupler for use with modular prosthetic trauma, or other medical implants wherein the components are fabricated from different compositions with different electrochemical potentials. For example, one module of Co-Cr-Mo alloy and another of Ti-6A1-4V or 316L stainless steel; or cold-worked 316L stainless steel (such as a bone screw) used with a hot-worked or less severe cold-worked 316L stainless steel (such as a bone plate). The invention interpositional coupler provides either a direct electrical connection or an insulative laver between the modules of differing electrochemical potentials so that an electrical current cannot flow from one module to the other through the body fluids, which act as an electrolyte, and thereby inhibits potential galvanic action.

The coupler according to the invention is advantageous in that it will prevent the build up of galvanic charge and it may be utilised as an interposing fit between the neck of a prosthetic hip joint stem and the bore hole in the femoral head cooperating with said neck; an interposing fit between modules of a modular knee joint, eg, in which case the coupler may be substantially rectangular in shape; an interposing fit between a tibial post and an extension post in a modular knee prosthesis; or an interposing fit between a bone plate and a screw for holding said bone plate in position.

Figure 1 is a schematic representation of a modular hip joint with an interpositional coupler.

Figure 1A is a schematic of an insulative coated coupler in partial cross-section.

Figure 2 is a schematic representation of a modular knee joint.

Figure 3 is a schematic representation of a bone crew and bone plate with an interpositional coupler. In an example of the first embodiment, the present invention provides a dual composition coupler or sleeve for interposing between the neck of a prosthetic femoral stem component and the borehole of metallic femoral head component to reduce or eliminate potentially adverse effects from galvanic corrosion.

With reference to Figure 1 there is illustrated the components of a modular hip joint prosthesis which conventionally includes a femoral head 10 and a hip joint stem body 40. The invention now adds an additional component, a dual composition sleeve 20 that is interposed between the neck 42 and femoral head 10. The dual composition sleeve 20 is composed of two nested thin sleeves. Sleeve 32 will nest into sleeve 30, as shown in Fig 1B, so that the outer surface 34 or sleeve 32 nests in and is coextensive with the inner surface 36 of sleeve 30. These two sleeves are then bonded together by any conventional metallic bonding process such as friction welding, high temperature diffusion bonding, brazing, and the like to eliminate any gaps between surfaces 34 and 36 which may be invaded by body fluids that act as electrolytes.

In the conventional modular hip joint prosthesis, the femoral head 10 is fabricated of a hard metallic alloy, preferably a cobalt chrome alloy, that is resistant to wear. The femoral head 10 has a borehole 12 with an inner surface 14 tapered at an angle a, the conventional non-cemented hip joint stem, preferably fabricated from Ti-6A1-4V, has a body 40 supplied with a neck 42. The proximal end 44 of the neck 42 is tapered at an angle B, the interpositional dual composition sleeve of the invention 20 has an outer surface 38 tapered at an angle of about α for cooperating with the borehole 12 in the femoral head. Further, the dual composition sleeve 20 has an inner surface 22 tapered at an angle of about \$ for cooperating with the outer surface of the tapered proximal end portion 44 of the neck 42. Thus, when assembled, the dual composition sleeve fits tightly into the femoral head and tightly over the proximal end of the neck thereby mechanically coupling the hip joint stem 40 to the femoral head 10.

When the invention modular hip joint prosthesis described above is implanted into a patient, the presence of the dual composition sleeve prevents potential galvanic corrosion within the Interface between the femoral head and the hip joint stem by providing similar metals at the head-sleeve and stem neck-sleeve contact points.

As an alternative, the interpositional insulative sleeve 50 shown in Figure 14 may be used. This sleeve is fabricated from zirconium or a zirconium aloly core 32 the surfaces \$4 of which has been coated with blue-black or black zirconium oxide or zirconium nitride to a depth of about \$5 microns or less. This sleeve insulates the head from the stem thereby preventing potential galvanic action. As a further alternative, the interpositional sleever may be fabricated from any suitable metal coated with a ceramic such as an oxide or nitride or an amorphous diamond-like carbon coating.

From Figure 2, the essential modular components of a knee joint prosthesis include a primary femoral component 112, which cooperates with a tibial component 113. The femoral component 112 is a generally J-shaped member and includes a pair of laterally spaced apart femoral condyle portions 114 and 116, each of which is smoothly, convexly curved in lateral profile similar to the curvature of the anatomical femoral condyle. The tibial component 113 comprises a tibial base portion 115 for accommodating and affixing a tibial platform 117 thereon. The tibial base portion 115 includes a floor portion 118 configured to resemble the overall configuration of the upper end portion of the tibia which is prepared to receive the base portion. The base portion 115 includes a stabilizing post 123 extending from its inferior surface and insertable into the tibial medulary canal to provide for stabilizing the component on the tibia. This post 123 may also have an extension portion which is fit tightly onto the post. An invention sleeve 195 may also be used to galvanically isolate the tibial post 123 from the extension post 196, as shown in Figure 2. Platform 117 is shaped generally in the configuration of base portion 115, and is designed to fit onto platform 115. Further, a centrally located stabilizer post 143 may be positioned on the upper face of tibial platform 117 for knee stability if the posterior cruciate ligament is removed. When a stabilizer post is used, the femoral component must be modified to engage this post and provide stability.

To accommodate a modular adapter component, the femoral modular platform 140 includes a base portion 145 joined to a pair of spaced apart platform portions 146 and 148. Each of the base portions include a bore 152 for receiving pin members 154 and 156 which are mounted on condyle portions 114 and 116 and extend upwardly from surfaces 132. These pin members 154 and 156 are aligned with bores 152 to enable platform 140 to be secured to primary femoral component 112. One of the modular components may include a rectangular plate 170 which is positioned as seen in Figure 2 on the face portions 146 and 148 of platform 170. These plates 170 include a bore 173 for allowing pin members 156 and 154 to be secured therethrough. As can be readily seen, it may be desirable to fabricate femoral component 112 from a different metallic alloy than platform 140. Furthermore, rectangular modular plates 170 may be fabricated from yet a different metallic alloy. Finally, the tibial platform 115 may also be fabricated by a different metallic alloy. Usually, the receiving tibial platform 117 is fabricated from ultra-high molecular weight polyethylene.

For the modular attachment of femoral knee components, dual compositional inserts may be interposed between the interfaces of any of these components. For example, inserts 190 and 191 may be used to galvanically separate the module 140 and nut 193,

and the module 140 or femoral component 112, respectively. These dual-composition components may have one side of a metal essentially matching the composition of the metal it mates with (eg. T ialloy femoral module) and the other side of a metal essentially matching the composition of the metal of the counter-mating component (eg. Co-Cr-Mo femoral component). Alternatively, the dual compositional sleeve or separator may be a metal substrate which has an inert, dense oxide or nitiride ceramic surface layer or amorphous diamond-like carbon surface layer

Further, screws may be used to anchor the tibial base plate to the bone by inserting through countersunk bore holes in the tibial base plate beneath the tibial platform 117. This assembly is similar in cross section to that shown in Figure 3 for the bone plate and bone screw trauma implant. Thus, a screw module 200 is driven through bone plate module 202 and holds the bone plate in place. An interpositional coupler 204 is interposed between the screw 200 and plate 202. This coupler 204 comprises an outside sleeve surface 206 the same as the metal of the plate 202 and an inner metal sleeve 208 the same as the metal of the screw 200. Alternatively, the screw 200 or bone plate 202 or both may be fabricated from zirconjum or a zirconjum alloy and maybe coated with a blue-black or black zirconium oxide or zirconium nitride coating. As a further alternative, either the screw or the bone plate or both may be coated with an oxide or nitride ceramic or an amorphous diamond-like carbon coating. This type of coupler will insulate screw from bone thereby preventing potential galvanic action

The invention has been described with reference to its preferred embodiment. One of ordinary skill in the art, upon reading the above disclosure, may comprehend changes and modifications that are within the scope of the specification as set forth above and the daims herabelow.

Claims

 A dual composition coupler for interposing between two components of a modular medical implant adapted for coupling with a first and a second component, comprising:

a first portion comprising a first metallic alloy that has an electrochemical potential susbatantially identical to that of the first component and

a second portion comprising a material different from the first metallic alloy which material prevents the build up of a galvanic charge between the first component and the second component. 2. A coupler according to claim 1 comprising:

an outer first portion adapted for coupling with a first component, the outer portion comprising a first metallic alloy that has an electrochemical potential substantially identical to that of the first component against which the outer portion is designed to couple; and

an inner second portion comprising a second metallic alloy different from the first metallic alloy the second metallic alloy having substantially the same electrochemical potential as the second component against which the surface of the inner portion is designed to fit.

- A coupler according to claim 2 comprising an inner sleeve and an outer sleeve.
 - A dual composition coupler for interposing between two components of a modular medical implants comprising;

(a) an outer sleeve portion having an outer surface adapted for coupling with a first component module, said outer surface comprising a first metallic alloy that has an electrochemical potential substantially identical to that of a first modular implant part against which the outer surface is designed to couple; and

(b) an inner sleeve portion comprising a second metallic alloy different from the first alloy, the outer surface of said inner sleeve portion being co-extensive with and nested tightly against the inner surface of the outer sleeve portion so that electrolyte solutions are precluded from entering between the inner and outer sleeve portion, the second alloy having substantially the same electrochemical potentials as second modular implant part against which the inner surface of the inner sleeve portion is designed to fit is designed to fit.

- 5. A coupler according to daims 3 or 4 wherein the inner surface of the inner sleeve portion is adapted to fit over the neck of a prosthetic hip joint stem and the outer surface of the outer sleeve portion is adapted to fit within the bore in a femoral head.
- 6. A coupler according to claims 3 or 4 wherein the inner surface of the inner sleeve portion is adapted to cooperate with the grooves of a screw and the outer surface of the outer sleeve portion is adapted to cooperate with a hole in a bone plate.
- A coupler according to claim 1 in which the first portion is coated with a layer of material which prevents the build up of galvanic charge between the first component and the second component on its component facing surfaces.

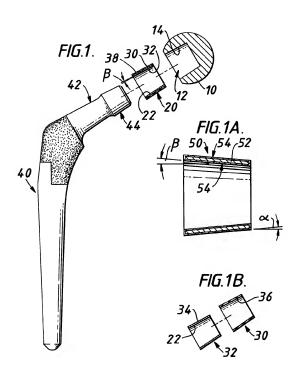
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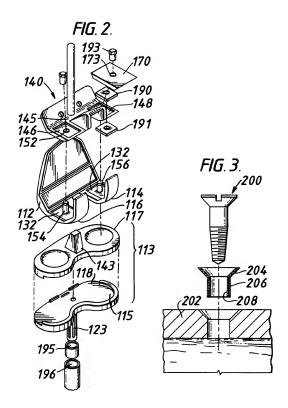
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- A coupler according to claim 1 comprising a first metallic alloy core and a surface coating over the core of a material which prevents the build up of galvanic charge between the first component and the second component.
- A coupler according to claims 7 or 8 in which the material which prevents the build up of galvanic charge between the first component and the second component is a ceramic.
- 10. A dual composition osupler comprising an insulative sleeve for interposing between components of a modular medical implant, which sleeve comprises a zirconium or zirconium alloy metal substrate core and an in situ formed surface coating over said substrate core, said coating selected from the group of coatings consisting of bueback zirconium oxide, zirconium nitride and carbon coatings, said sleeve being designed for interposing if the between two modules comprising materials of different electrochemical potential that the other such that, when said sleeve is interposed between the modules the sleeve insulates the two modules, from each other thereby substantially reventing advante action.
- 11. A coupler according to claims 7 or 10 wherein the sleeve is designed for interposing fit between the neck of a prosthetic hip joint stem and the bore hole in the femoral head cooperating with said neck.
- 12. A coupler according to claims 7 or 10 wherein the sleeve is designed to fit between a bone plate and a screw for holding said bone plate in place.
- A coupler according to claim 2 which is an interpositional coupler.
- 14. An interpositional coupler for inserting in a modular medical implant, said coupler shaped to fit between a first module having a surface designed to fit against a surface of a second module, said coupler comprising; a first surface, having a metallic composition identical to the metallic composition of the first module and adapted to fit snugly against the fitting surface of the first module; and a second surface having a metallic composition identical to the composition of the fitting surface of the second module and adapted to fit snugly against the fitting surface of the second module, so that when the coupler is inserted between the first and second modules in the body of a patient then galvanic activity between the metallic compositions of the first and second modules is effectively prevented.

- 15. A coupler according to claims 13 or 14 wherein the coupler is of a substantially rectangular shape for interposing between modules of a modular knee joint.
- 16. A coupler according to claims 13 or 14 wherein the coupler is of substantially cylindrical shape for interposing between a tibial post and an extension post in a modular knee prosthesis.
- 17. A coupler according to claims 13 or 14 wherein the coupler is shaped to interpose between the surface of a hole in a bone plate and the surface of a screw that fits into the hole interposed with the coupler.
- A coupler according to claim 1 having a surface and comprising a first metal alloy from which the coupler is fabricated and a coating over the surface of the coupler, said coating selected from the group of coatings consisting of amorphous diamond-like carbon, metal nitrides and metal coxidess.
 - 19. An insulative coupler for interposing between modules of a modular medical implant, said coupler having a surface and comprising a metal substate from which the coupler is abtricated and a coating over the surface of the coupler, said coating selected from the group of coatings consisting of amorphous diamond-like carbon, metal nitrides and metal oxides, so that when the coupler is interposed between two modules of a modular implant in the body of a patient, said modules comprising materials of different electrochemical potential, then the coupler prevents galvanic action between the modules.
 - 20. A coupler according to claims 18 or 19 wherein the coupler is shaped to fit over the neck of a prosthetic hip joint stem module and into a receiving hole in a femoral head module thereby interposing between the surfaces of the neck and the receiving hole.
- 21. A coupler according to claims 18 or 19 wherein the coupler is shaped to interpose between a surface of a hole in a bone plate and a surface of a screw for affixing the bone plate.
- 22. A coupler according to claims 18 or 19 wherein the coupler is of an annular cylindrical shape for interposing between a tibial post and an extension post in a modular knee prosthesis.
- 23. A coupler according to claims 18 or 19 wherein the coupler is of a substantially rectangular shape of finite thickness for interposing between modules of a modular knee prosthesis.

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